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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE er the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. **Application Number** 09/752,712 Filing Date TRANSMITTAL December 28, 2000 First Named Inventor **FORM** James E. Parker Art Unit 1743 **Examiner Name** Samuel P. Siefke (to be used for all correspondence after initial filing) Attorney Docket Number VTECH-48514 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance Communication to TC Fee Transmittal Form Drawing(s) Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to TC Petition (Appeal Notice, Brief, Reply Brief) Amendment/Reply Petition to Convert to a Proprietary Information After Final **Provisional Application** Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Identify **Terminal Disclaimer Extension of Time Request** below): Return Postcard Request for Refund **Express Abandonment Request** CD, Number of CD(s) Information Disclosure Statement Landscape Table on CD Certified Copy of Priority Remarks Document(s) Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name Fulwider Patton LLP Signature Printed name David G. Parkhurst Date Reg. No. May 8, 2007 29,422 CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

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RESPONSE UNDER 37 CFR 1.116 EXPEDITED PROCEDURE EXAMINING GROUP 1743

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

JAMES E. PARKER

Serial No. 09/752,712

Filed: December 28, 2000

For: DRUG TEST KIT

Examiner: Samuel P. Siefke

Group Art Unit: 1743

Docket No.: VTECH-48514

May 8, 2007

Los Angeles, California 90045

AMENDED APPEAL BRIEF

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Amended Appeal Brief is being filed in response to the Notification of Non-Compliant Appeal Brief dated April 9, 2007, for which a response is due by May 9, 2007. A Notice of Appeal was filed on August 4, 2006, from the final rejection dated March 7, 2006. An Appeal Brief was filed on October 4, 2006, within the term provided as permitted under 37 C.F.R. § 41.37(a)(1). This Amended Appeal Brief corrects the

headings and order for items as prescribed in 37 CFR 41.37(c), and identifies the claims that are on appeal.

I. REAL PARTY IN INTEREST

The real party in interest is MODERN OPTICS, INC. This application was assigned by the inventor, JAMES E. PARKER to MODERN OPTICS, INC., by an assignment executed December 5, 2000, which was recorded by the Patent Office on December 28, 2000, at reel 011703, frame 0977.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-14, 17, 19, 22 and 24-31 are cancelled. Claims 15, 16, 18, 20, 21 and 23 are rejected. Claims 15, 16, 18, 20, 21 and 23 are being appealed.

IV. STATUS OF AMENDMENTS

No amendment of the claims was filed subsequent to the final rejection of March 7, 2006. The claims were most recently amended in the Amendment of December 9, 2005, which was entered.

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V. SUMMARY OF CLAIMED SUBJECT MATTER

The embodiment of the invention currently claimed in independent Claims 15 and 20 is depicted in Figs. 4-5, and is described in detail in the specification at page 8, line 17, to page 9, line 9.

As is recited in independent Claim 15, the assaying apparatus (60, Fig. 4) for collecting and analyzing a liquid sample for an analyte in the liquid sample includes a container (62, Fig. 4) having an interior sample chamber (64, Fig. 4) with a liquid sample space, and the container (62, Fig. 4) has a surface defining an opening in communication with the interior sample chamber (64, Fig. 4). The assaying apparatus (60, Fig. 4) also includes a cap (68, Figs. 4 and 5) adapted to be placed on the container (62, Fig. 4) opening for closing the container (62, Fig. 4) opening and sealing the container (62, Fig. 4). An assay strip (70, Fig. 5) is disposed in the cap (68, Figs. 4) and 5), and the assay strip (70, Fig. 5) has an assay region (72, Fig. 5) disposed in the cap (68, Figs. 4 and 5) for indicating the presence or absence of an analyte in a liquid sample placed in the liquid sample space of the interior sample chamber (64, Fig. 4). The cap (68, Figs. 4 and 5) includes a separator member (84, Fig. 5) disposed between the assay strip (70, Fig. 5) and the interior sample chamber (64, Fig. 4) for separating the liquid sample space from the assay region (72, Fig. 5) of the assay strip (70, Fig. 5). A wick (78, Fig. 4) is mounted to the cap (68, Figs. 4 and 5) and extends into the liquid sample space of the interior sample chamber (64, Fig. 4) when the cap (68, Figs. 4 and 5) is placed on the container (62, Fig. 4). The wick (78, Fig. 4) is in fluid communication with the assay strip (70, Fig. 5) for conducting a portion of the liquid

sample from the interior sample chamber (64, Fig. 4) to the assay region (72, Fig. 5) of the assay strip (70, Fig. 5). An annular bridging wick piece (80, Fig. 5) is connected between the wick (78, Fig. 4) and the assay strip (70, Fig. 5) and in fluid communication with the wick (78, Fig. 4) and the assay strip (70, Fig. 5), and in immediate contact with the assay strip (70, Fig. 5) for conducting the liquid sample from the wick (78, Fig. 4) to the assay strip (70, Fig. 5).

As is recited in independent Claim 20, the assaying apparatus (60, Fig. 4) for collecting and analyzing a liquid sample for the presence or absence of a plurality of analytes in the liquid sample includes a container (62, Fig. 4) having an interior sample chamber (64, Fig. 4) with a liquid sample space, and the container (62, Fig. 4) has a surface defining an opening in communication with the interior sample chamber (64, Fig. 4). The assaying apparatus (60, Fig. 4) includes a cap (68, Figs. 4 and 5) adapted to be placed on the container (62, Fig. 4) opening for closing the container (62, Fig. 4) opening and sealing the container (62, Fig. 4). A plurality of assay strips (70, Fig. 5) are disposed in the cap (68, Figs. 4 and 5), with each assay strip (70, Fig. 5) having an assay region (72, Fig. 5) disposed in the cap (68, Figs. 4 and 5) for indicating the presence or absence of one of a plurality of analytes in a liquid sample placed in the liquid sample space of the interior sample chamber (64, Fig. 4). The cap (68, Figs. 4 and 5) includes a separator member (84, Fig. 5) disposed between the assay strips (70, Fig. 5) and the interior sample chamber (64, Fig. 4) for separating the liquid sample space from the assay region (72, Fig. 5) of the assay strips (70, Fig. 5). A wick (78, Fig. 4) is mounted to the cap (68, Figs. 4 and 5) and extends into the liquid sample space of

the interior sample chamber (64, Fig. 4) when the cap (68, Figs. 4 and 5) is placed on the container (62, Fig. 4). The wick (78, Fig. 4) is in fluid communication with the assay strips (70, Fig. 5) for conducting a portion of the liquid sample from the interior sample chamber (64, Fig. 4) to the assay region (72, Fig. 5) of the assay strips (70, Fig. 5). An annular bridging wick piece (80, Fig. 5) is connected between the wick (78, Fig. 4) and the assay strips (70, Fig. 5) and in fluid communication with the wick (78, Fig. 4) and the assay strips (70, Fig. 5) and in immediate contact with the assay strips (70, Fig. 5) for conducting the liquid sample from the wick (78, Fig. 4) to the assay strips (70, Fig. 5).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the final Office Action of March 7, 2006, Claims 18 and 23 were objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to limit the subject matter of a previous claim. The Examiner indicated that Claims 15 and 20 have limitations of an assay strip comprising a wicking material.

Claims 15-16, 18, 20, 21 and 23 were rejected under 35 U.S.C. 103(a) on the grounds of obviousness from U.S. Patent No. 6,627,152 to Wong in view of U.S. Patent No. 6,168,758 to Forsberg et al. and U.S. Patent No. 5,501,837 to Sayles. Wong was cited as disclosing a wick mounted to the cap and extending the liquid sample space of the interior sample chamber when the cap is placed on the container. Forsberg et al. was cited as disclosing wick pads 4 in contact with wicks 3 and that are used to transfer

sample liquid 30 from the reservoir 18 by the wicks 3 to test strips 5. The Examiner acknowledged that Wong does not teach using an "annular" bridging member to link the assay strip to the wicking member, but argued that the wick pads 4 of Forsberg et al. constitute an annular bridging wick piece as recited in Claims 15 and 20, and that it would have been obvious to modify Wong to use the wick pads 4 of Forsberg et al. to provide an "annular" bridging wick piece. Sayles was cited as disclosing an annular wick 38 in contact with test strips 32. The Examiner further argued that it would have been obvious to modify Wong to use the absorbent pad 38 of Sayles to provide an "annular" bridging wick piece.

VII. ARGUMENT

A. THE ISSUES FOR DETERMINATION

In view of the Examiner's rejections and arguments, Appellant respectfully submits that the issues on appeal are as follows:

- 1) Do Claims 15 and 20 recite an assay strip comprising a wicking material?
- 2) Does the prior art cited disclose a wick mounted to the cap of a container and extending into the liquid sample space of the interior sample chamber when the cap is placed on the container, as is recited in Claims 15 and 20?

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3) Does the prior art cited disclose an annular bridging wick piece connected between a wick and an assay strip or strips in fluid communication with the wick and the assay strip or strips, and in immediate contact with an assay strip or strips for conducting a liquid sample from the wick to the assay strip or strips, as is recited in Claims 15 and 20?

B. THE OBJECTION TO CLAIMS 18 AND 23 FOR FAILING TO LIMIT THE SUBJECT MATTER OF A PREVIOUS CLAIM

1. CLAIM 15 DOES NOT RECITE AN ASSAY STRIP COMPRISING A WICKING MATERIAL

The Examiner objected to Claim 18 on the grounds that Claim 15 already has limitations for an assay strip comprising a wicking material for conducting the liquid sample from the wick to the assay region of the assay strip. Claim 18 recites "wherein said assay strip comprises wicking material for conducting the liquid sample from said wick to said assay region of said assay strip."

Claim 15 recites "an assay strip disposed in said cap, said assay strip having an assay region disposed in said cap for indicating the presence or absence of an analyte in a liquid sample placed in said liquid sample space

of said interior chamber, and said cap including a separator member disposed between said assay strip and said interior sample chamber for separating said liquid sample space from said assay region of said assay strip." Claim 15 does not recite that the assay strip comprises wicking material for conducting the liquid sample from the wick to the assay region of the assay strip, as asserted by the Examiner. It is therefore respectfully submitted that the Examiner's objection to Claim 18 was in error, and that the objection to claim 18 should be withdrawn.

2. CLAIM 20 DOES NOT RECITE AN ASSAY STRIP COMPRISING A WICKING MATERIAL

The Examiner objected to Claim 23 on the grounds that Claim 20 already has limitations for an assay strip comprising a wicking material for conducting the liquid sample from the wick to the assay region of the assay strip. Claim 23 recites "wherein said assay strips comprise wicking material for conducting the liquid sample from said wick to said assay regions of said assay strips."

Claim 20 recites "a plurality of assay strips disposed in said cap, each assay strip having an assay region disposed in said cap for indicating the presence or absence of one of a plurality of analytes in a liquid sample placed in said liquid sample space of said interior chamber, and said cap

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including a separator member disposed between said assay strips and said interior sample chamber for separating said liquid sample space from said assay region of said assay strip." Claim 20 does not recite that the assay strips comprise wicking material for conducting the liquid sample from the wick to the assay region of the assay strip, as asserted by the Examiner. It is therefore respectfully submitted that the Examiner was in error, and that the objection to claim 23 should be withdrawn.

C. THE REJECTION OF CLAIMS 15-16, 18, 20, 21 AND 23 AS OBVIOUS

1. WONG, FORSBERG ET AL. AND SAYLES DO NOT
DISCLOSE A CAP WITH TEST STRIP END PORTIONS
EXTENDING INTO A CONTAINER INTERIOR SAMPLE
CHAMBER LIQUID SAMPLE SPACE WHEN A CAP IS
PLACED ON THE CONTAINER

Regarding the rejection of Claims 15-16, 18, 20, 21 and 23, it is respectfully submitted that Wong, Forsberg et al. and Sayles do not teach, disclose or suggest test strip end portions that extend into the liquid sample space of the interior sample chamber when the cap is placed on the container. Claims 15 and 20 recite "a container having an interior sample chamber with a liquid sample space," and "a wick mounted to said cap

and extending into said liquid sample space of said interior sample chamber when said cap is placed on said container."

Wong was cited as disclosing a wick that extends into a sample when the cap is on the container, and the Examiner referred to Fig. 8 of Wong. Fig. 8 of Wong shows a vessel 20 with fluid 130 in the vessel, and it is clear that the end portion 122 of each test strip 120 does not extend into the fluid 130 in the vessel. As is illustrated in Fig. 5 of Wong, and as described at column 4, lines 28-40, the end portion 122 of each test strip 120 exits through an exit port 90, and the end portions 122 and the exit ports 90 are surrounded by the rim 92 on the bottom side 78 of the cap. In Wong, the end portions 122 of each test strip do not extend into the liquid sample space 130 of the interior sample chamber 38 when the cap is placed on the container. As is described in Wong at column 3 line 50, to column 4, line 44, the carrier 50 is provided to bring liquid sample up to the test strip end portions 122, because the test strip end portions do not extend into the liquid sample space of the interior sample chamber when the cap is placed on the container.

Forsberg et al. was not cited as disclosing a wick that extends into a sample when the cap is on the container. Figs. 3 and 16 of Forsberg et al. show a container 25, 200, with a liquid sample 30, 202, with wicks 3, 120 in the cap and separated from the liquid sample space in the container by the base of a reservoir 18, and a wick chamber 118.

Sayles was not cited as disclosing a wick that extends into a sample when the cap is on the container. Sayles discloses reagent strips 32 that are directly in contact with the

<u>fluid supply</u> through the test chambers 34 and windows 24, 26, and does not disclose wick that extends into a sample when the cap is on the container.

It is therefore respectfully submitted that Wong, Forsberg et al. and Sayles, taken either individually or in combination, do not teach, disclose or suggest wick mounted to the cap of a container and extending into the liquid sample space of the interior sample chamber when the cap is placed on the container, as is recited in Claims 15 and 20.

2. THE PRIOR ART CITED DOES NOT DISCLOSE AN
ANNULAR BRIDGING WICK PIECE ADJACENT TO AND
IN FLUID COMMUNICATION WITH A WICK, AND IN
IMMEDIATE CONTACT WITH AN ASSAY STRIP OR
STRIPS FOR CONDUCTING A LIQUID SAMPLE FROM
THE WICK TO THE ASSAY STRIP OR STRIPS

Claim 15 recites "an annular bridging wick piece connected between said wick and said assay strip in fluid communication with said wick and said assay strip and in immediate contact with said assay strip for conducting the liquid sample from said wick to said assay strip." Claim 20 similarly recites "an annular bridging wick piece connected between said wick and said assay strips in fluid communication with said wick and said assay strips and in immediate contact with said assay strips for conducting the liquid sample from said wick to said assay strips."

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The Examiner acknowledged that Wong does not teach using an "annular" bridging member to link the assay strip to the wicking member. The Examiner argued that Forsberg et al. discloses wick pads 4 that constitute an annular bridging wick piece as recited in Claims 15 and 20, and that it would have been obvious to modify Wong to use the wick pads 4 of Forsberg et al. to provide an "annular" bridging wick piece. The Examiner cited Webster's Ninth New Collegiate Dictionary as defining "annular" as "of, relating to, or forming a ring." The Examiner did not assert that the wick pads 4 of Forsberg et al. form a "ring," and did not assert what part of the definition of "ring" applied to the four spaced apart wick pads 4 of Forsberg et al. Fig. 2 of Forsberg et al. discloses four wick rounded flattened wick pads arranged in a squared pattern. The Examiner does not assert that the squared pattern of wick pads forms a ring, but indicates that the wick pads 4 of Forsberg et al. perform the same function as an annular bridging wick piece. However, Fig. 2 clearly shows that the four wick pads 4 of Forsberg et al. would connect separately with four test strips 5, so that the four different wick pads 4 can convey liquid sample non-uniformly, and with differing effectiveness, whereas the annular bridging wick piece 78 of the present invention will convey liquid sample uniformly and with the same effectiveness, because the annular bridging wick piece 78 does form a ring. Therefore the four wick pads 4 of Forsberg et al. do not perform the same function as the annular bridging wick piece of the present invention, and that Forsberg et al. does not teach, disclose or suggest an annular bridging wick piece connected between a wick and an assay strip in fluid communication with the wick and

the assay strip and in immediate contact with the assay strip for conducting the liquid sample from the wick to the assay strip, as is claimed.

Sayles was cited as disclosing an annular wick 38 in contact with test strips 32, and the Examiner argued that it would have been obvious to modify Wong to use the absorbent pad 38 of Sayles to provide an "annular" bridging wick piece. Sayles discloses an absorbent pad 38 which is annular that is not connected between a wick and an assay strip in fluid communication with the wick and the assay strip and in immediate contact with the assay strip for conducting the liquid sample from the wick to the assay strip, but instead aids in drawing fluid from protruding ends of reagent strips along the lengths of the reagent strips by capillary action. Placing the annular wick 38 of Sayles at the ends of the test strips 120 of Wong to draw fluid from the test strips of Wong would not result in the present invention. Placing the annular wick 38 of Sayles at the other ends of the test strips 120 of Wong would serve no function, because Wong discloses at column 4, lines 33-36, that "pads disposed at the end 122 of the strip 120" already "contact the middle portion 125 of the strip 120, such that the strip functions properly." These pads disposed at the end 122 of the strip 120 of Wong are shown in Fig. 4 to be the wicks that extend into a fluid sample when the fluid sample is lifted up by the carrier 50, and these pads disposed at the end 122 of the strip 120 of Wong directly wick fluid to the test strips 120, so that an annular bridging wick piece would serve no function in Wong.

It is therefore respectfully submitted that Wong, Forsberg et al. and Sayles, taken either individually or in combination, do not teach, disclose or suggest an annular bridging wick piece connected between a wick and an assay strip in fluid communication

with the wick and the assay strip and in immediate contact with the assay strip for conducting the liquid sample from the wick to the assay strip, as is recited in Claims 15 and 20.

D. CONCLUSION

For the foregoing reasons, it is submitted that the Examiner's objections to Claim 18 and 23 were erroneous; that the present invention as claimed is not rendered obvious from U.S. Patent No. 6,627,152 to Wong in view of U.S. Patent No. 6,168,758 to Forsberg et al. and U.S. Patent No. 5,501,837 to Sayles, and that the Examiner's rejections of 15-16, 18, 20, 21 and 23 were therefore erroneous.

Appellant respectfully requests reversal of the objections to Claims 18 and 23 and the rejection of 15-16, 18, 20, 21 and 23.

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The fee for the appeal brief was previously provided with the filing of the appeal brief on October 4, 2006. Please charge any additional fee that may be required to our Deposit Account No. 06- 2425.

Respectfully submitted,

FULWIDER PATTON LLP

By:

David G. Parkhurst Reg. No. 29,422

DGP/eab

Encls.: VIII. CLAIMS APPENDIX

IX. EVIDENCE APPENDIX

X. RELATED PROCEEDINGS APPENDIX

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VIII. CLAIMS APPENDIX

15. Assaying apparatus for collecting and analyzing a liquid sample for an analyte in the liquid sample, the apparatus comprising:

a container having an interior sample chamber with a liquid sample space, said container having a surface defining an opening in communication with said interior sample chamber;

a cap adapted to be placed on said container opening for closing said container opening and sealing said container;

an assay strip disposed in said cap, said assay strip having an assay region disposed in said cap for indicating the presence or absence of an analyte in a liquid sample placed in said liquid sample space of said interior chamber, and said cap including a separator member disposed between said assay strip and said interior sample chamber for separating said liquid sample space from said assay region of said assay strip;

a wick mounted to said cap and extending into said liquid sample space of said interior sample chamber when said cap is placed on said container, said wick being in fluid communication with said assay strip for conducting a portion of the liquid sample from said interior chamber to said assay region of said assay strip; and

an annular bridging wick piece connected between said wick and said assay strip in fluid communication with said wick and said assay strip and in immediate contact with said assay strip for conducting the liquid sample from said wick to said assay strip.

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- 16. The assaying apparatus of Claim 15, further comprising a transparent cover over said assay strip permitting observation of the results of the assay.
- 18. The assaying apparatus of Claim 15, wherein said assay strip comprises wicking material for conducting the liquid sample from said wick to said assay region of said assay strip.
- 20. Assaying apparatus for collecting and analyzing a liquid sample for the presence or absence of a plurality of analytes in the liquid sample, the apparatus comprising:

a container having an interior sample chamber with a liquid sample space, said container having a surface defining an opening in communication with said interior sample chamber;

a cap adapted to be placed on said container opening for closing said container opening and sealing said container;

a plurality of assay strips disposed in said cap, each assay strip having an assay region disposed in said cap for indicating the presence or absence of one of a plurality of analytes in a liquid sample placed in said liquid sample space of said interior chamber, and said cap including a separator member disposed between said assay strips and said interior sample chamber for separating said liquid sample space from said assay region of said assay strip;

a wick mounted to said cap and extending into said liquid sample space of said interior sample chamber when said cap is placed on said container, said wick being in

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fluid communication with said assay strip for conducting a portion of the liquid sample from said interior chamber to said assay region of said assay strip; and

an annular bridging wick piece connected between said wick and said assay strips in fluid communication with said wick and said assay strips and in immediate contact with said assay strips for conducting the liquid sample from said wick to said assay strips.

- 21. The assaying apparatus of Claim 20, further comprising a transparent cover over said assay strips permitting observation of the results of the assays.
- 23. The assaying apparatus of Claim 20, wherein said assay strips comprise wicking material for conducting the liquid sample from said wick to said assay regions of said assay strips.

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IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

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